

REMARKS

Reconsideration is requested.

The specification has been amended as suggested by the Examiner on page 4 of the Office Action dated November 20, 2003 (Paper No. 12).

The details of claim 70 have been added to claim 69, from which claim 70 depended. Claims 70, 80, 90 and 100 have been canceled, without prejudice, to advance prosecution. Claim 106 has been added and reads on the elected subject matter. Claim 106 is similar to amended claim 69. No new matter has been added.

The Examiner has indicated that the restriction and species election requirements of the Office Action dated June 27, 2003 (Paper No. 10) have been maintained and made FINAL. The applicants elected, with traverse, the subject matter of the Examiner's Group I (claims 65-74 and 85-94 "drawn to a plurality of independent and distinct isolated DNAs of Neisseria") and elected the product of claim 70 ("The isolated DNA or complement of claim 69, said DNA sequence of Region 4 hybridizing with SEQ ID NO: 95.") as a single disclosed product, in response to the Examiner's additional requirement in ¶4 of Paper No. 10.

The Examiner has stated in Paper No. 12 that "**Claims 69-70 and 89-90 are under consideration; all other claims stand withdrawn from consideration.**" See, page 3 of Paper No. 12 (emphasis in original).

Claim 70, and claim 90 which is dependent there from, of the unamended claims recited the elected species. Claim 70, which was dependent on claim 69, has been canceled, to advance prosecution and the details of the same have been inserted in to

the above-amended claim 69. Claims 90 and 100 have been similarly canceled, to advance prosecution.

The Examiner's reminder regarding rejoinder of process claims is acknowledged, with appreciation. There are no pending method or process claims. The applicants reserve the right to pursue further disclosed and unclaimed and/or unexamined subject matter in further divisional applications.

The Section 112, first paragraph, rejection of claims 69, 70, 89 and 90, stated on pages 5-7 of Paper No. 12 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the above amendments and the following comments.

Initially, the Examiner is urged to appreciate that the presently claimed invention provides DNA sequences which may be used as a diagnostic tool for detecting the presence of *Neisseria meningitides* (Nm) (see, for example, page 1, lines 9-10; page 6, lines 1-3; and page 15, lines 7-29, of the specification) and specifically for distinguishing Nm from *Neisseria lactamica* (NI). The DNA molecules of the presently claimed invention may also be used to distinguish Nm- and Ng-specific sequences which are involved in the colonization of the nasopharynx or invasion of the submucosal space or systemic dissemination, i.e., and are related to virulence factors. See, page 5, lines 8-29 of the specification. The fact that the claimed sequences hybridize with both Nm and Ng sequences and not NI sequences is predictive of the sequences being involved in virulence of Nm and Ng. Neither of these embodiments of the presently disclosed invention are believed to require expression of an open reading frame, as appears to be suggested by the Examiner.

Claim 69 defines the claimed DNA sequence structurally and by its physical properties (i.e., hybridization conditions). The claimed invention is described in the specification in such a manner that one of ordinary skill in the art would appreciate that the applicants were in possession of the claimed invention at the time the application was filed.

The Examiner's reference to six (6) reading frames as an alleged basis for a lack of written description support (see, page 6 of Paper No. 12) is believed to be misplaced. Specifically, the applicants submit that the specification teaches, and the Examiner is believed to have acknowledged, that the sequence of SEQ ID NO:95 is a partial sequence of an open reading frame of the Nm genome. One of ordinary skill in the art will appreciate from the specification and the generally advanced level of skill in the art that the ORF containing SEQ ID NO:95 may be further identified, if required. The Examiner's concerns regarding the size of hybridizing DNA (see, page 7 of Paper No. 12) are, with due respect, believed to be misplaced as the recited hybridization conditions define the size and structural attributes of hybridizing DNA. The applicants again urge the Examiner to appreciate that the disclosed and claimed invention does not require, in the claimed embodiment which is under consideration, expression of a protein. The claims under consideration are submitted to be supported by an adequate written description. The applicants note that new claims 106 and 107 do not recite the language which is apparently troubling to the Examiner and allowance of at least claims 106 and 107 are requested.

Attached for completeness and exemplification is a copy of Perrin (Infection and Immunity, Dec. 2002, p. 7063-7072, Vol. 70, No. 12) which the applicants submit to

show that by using the claimed hybridization conditions, the gene NMA 0478 (see, Table 2 in the middle) was obtained. This article is submitted by the applicants to further demonstrates that the person of ordinary skill in the art was able to successfully practice the present invention. The applicants believe that there was no need for one of ordinary skill to require a complete ORF as the hybridization step will produce the same. The applicants submit that the hybridization does not lead to the isolation of a great number of genes.

Reconsideration and withdrawal of the Section 112, first paragraph, rejection is requested.

To the extent not obviated by the above amendments, the Section 112, second paragraph, rejection of claims 69-70 and 89-90 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the above and the following comments.

The preamble of claim 69 has been amended above to further indicate that the claimed DNA molecules hybridize with the noted Ng and Nm sequences under the recited conditions. The claimed DNA sequences do not hybridize with the noted NI sequences under the recited conditions.

Claim 69 clearly indicates that the recited complement of the claim is a complement of the claimed DNA.

Claim 69 is submitted to clearly identify the DNA molecules which are not a part of the claimed invention, such as is described at page 5, lines 15-17 of the present application.

Claim 69 does not include a recitation of region 4. The applicants believe however that the specification clearly defines region 4 of Z2491, for example, at page 9, lines 19-20, as being between arg J and reg F. Region 4 is clearly defined to one of ordinary skill in the art.

The recitations of claim 70 have been included in claim 69 to advance prosecution. The applicants note that the claimed invention also relates to RNAs, as recognized by the Examiner, and as described, for example, at page 10, lines 13-15 of the specification. Claim 69 and 106, for example, provide for an isolated DNA or a complement of the isolated DNA.

The claims under consideration are submitted to be definite. Withdrawal of the Section 112, second paragraph, rejection is requested.

The Section 102 rejections of claims 69 and 89 over each of Dempsey (Journal of Bacteriology, November 1995, Vol. 177(22), pages 6390-6400), Wolff (FEMS Microbiology Letters, January 1995), Martin (Accession No. M65216, created date May 2, 1992), Gaher (Molecular Microbiology, January 1996, Vol. 19(2), pages 249-259) and Dempsey (Journal of Bacteriology, April 1994, Vol. 176(7)), are obviated by the above amendments as the details of claim 70, which were indicated as being novel and patentable over the art of record, have been inserted in claim 69, and also recited in claim 106, to advance prosecution. Withdrawal of the Section 102 rejections are requested.

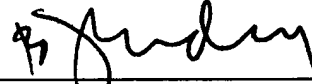
Claim 69, 89, 106 and 107 are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned however if anything further is required in this regard.

NASSIF et al
Appl. No. 09/928,457
May 19, 2004

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



B. J. Sadoff
Reg. No. 36,663

BJS
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100